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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/698,291 | 10/31/2003 | Martin T. Gerber | P-9492.00US | 1410 |
| 27581 | 7590 | 04/21/2005 | EXAMINER | |
| MEDTRONIC, INC. 710 MEDTRONIC PARKWAY NE MS-LC340 MINNEAPOLIS, MN 55432-5604 | | | | GREENE, DANA D |
| ART UNIT | | PAPER NUMBER | | |
| | | 3762 | | |

DATE MAILED: 04/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|----------------------------|------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 10/698,291 | GERBER ET AL. |
| | Examiner Dana D. Greene | Art Unit 3762 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 10/31/03.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-57 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1-57 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on 31 October 2003 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892)
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
 Paper No(s)/Mail Date 10-31-03.

4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date. _____.
 5) Notice of Informal Patent Application (PTO-152)
 6) Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 7-10, 22, 28-31, 42-51, and 53 stand rejected under 35 U.S.C. §102(b) as being anticipated by Starkebaum (US 5,733,322, hereinafter “Starkebaum”).

Starkebaum is considered to disclose:

a neurostimulation lead comprising a lead body having a proximal end and a distal end; one or more stimulation electrodes disposed adjacent to the distal end of the lead body (see col. 3, ln. 40-47 and fig. 8, Starkebaum). The disclosed neurological epidural lead is considered to anticipate the claimed neurostimulation lead because both structures have a proximal and distal end with a series of electrodes attached near the distal end, which make it feasible to deliver neurostimulation therapy to patients to treat a variety of symptoms and conditions;

a fixation mechanism mounted to the lead body at a position between one of the electrodes and the proximal end of the lead body (see col. 1, ln. 64 – col. 2, ln. 5, Starkebaum). The disclosed protruding structure is considered to anticipate the claimed fixation mechanism because both provide effective fixation of the implantable lead and avoid lead migration.

With reference to claim 22, Starkebaum is considered to disclose the elements as discussed above including:

an implantable neurostimulation pulse generator (see col. 4, ln. 1-5, Starkebaum). The disclosed IPG device is considered to anticipate the claimed pulse generator because both deliver therapy according to selected stimulation parameters;

an electrical conductor to electrically couple the implantable neurostimulation energy generator to a number of the electrodes (see col. 1, ln. 15-25, Starkebaum).

This prior art reference anticipates the claimed electrical conductor because Starkebaum teaches the application of electrical potential between pairs of electrodes through wires, which enables the coupling of the neurostimulation energy as, claimed.

With reference to claims 7, 9, 10, 30, 31, 42-51, Starkebaum is considered to disclose the method of inserting a lead introducer into a patient, inserting a lead into the patient via the introducer, and removing a restrain mechanism (see col. 6, ln. 50 – col. 7, ln. 15, Starkebaum). According to this prior art, the needle is removed leaving the lead in place (see col. 4, ln. 45-50, Starkebaum).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 4, 6, 12, 25, 27, 33, and 56 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Starkebaum in view of Sundquist et al. (US 6,567,704 B2, hereinafter "Sundquist"). Starkebaum is considered to disclose the claimed invention as discussed above, under the anticipatory rejection, except for the claimed shape memory alloy. However, Sundquist teaches this claimed shape memory alloy (see col. 8, ln. 37-40, Sundquist). It would have been obvious to one of ordinary skill in the art to combine the teachings of Starkebaum with the considered resilient material teaching found in Sundquist for the purpose of configuring the expandable wire-like elements in a substantial helical shape or other shape.

Also, claims 2, 3, 5, 11, 23, 24, 26, 32, 52, 54, 55, 57 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Starkebaum in view of Sundquist. Starkebaum is considered to disclose the claimed invention as discussed above, under the anticipatory rejection, except for the claimed elastic material. However Sundquist is considered to disclose this claimed elastic material (see col. 5, ln. 15-20, Sundquist). It would have been obvious to one of ordinary skill in the art to combine the teachings of

Starkebaum with the flexible material of Sundquist for the purpose of fixating the lad within a tissue site.

Claims 13-19, 21, and 34-40 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Starkebaum in view of Barreras, Sr. et al. (US 6,192,279 B1, hereinafter "Barreras"). The Starkebaum reference discloses the claimed invention as discussed above, under the anticipatory reference, except for the claimed rings. Barreras teaches this ring configuration (see col. 2, ln. 35-50, Barreras). It would have been obvious to one of ordinary skill in the art to combine the teachings of Starkebaum with those of Barreras for the purpose of retaining ends of the wire like elements.

Claims 20 and 41 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Starkebaum in view of Racz et al. (US 6,146,380, hereinafter "Racz"). Starkebaum discloses the claimed invention as discussed above, under the anticipatory rejection, except for the claimed fluoroscopic imaging. Racz is considered to disclose this claimed fluoroscopic imaging (see col. 4, ln. 45-50, Racz).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dana D. Greene whose telephone number is (703) 305-0851. The examiner can normally be reached on M-F 9-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (703) 308-5181. The fax phone number for the organization where this application or proceeding is assigned is (571) 272-4376.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Dana D. Greene
Dana D. Greene

George Manuel
George Manuel

Primary Examiner